

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative, Mr. David Kashman, on September 23, 2009.

The application has been amended as follows.

The claims are amended as follows.

11. (currently amended) The method of claim 19, characterised in that the ~~universal~~ primers ~~used in the amplification step~~ are ~~selected from the group consisting of:~~
5'TCCGGCATGTGCAAGGCCGG3' (SEQ ID NO:1) ~~and~~ 5'CTCCATGTCGTCCCAGTTGG3'
(SEQ ID NO: 2), 5'ACCAACTGGGACGACATGGAGAAGATCTGGC3' (SEQ ID NO: 3),
5'TACATGGCNGGGGTGTTAAAGGTCTCAAAC3' (SEQ ID NO: 4),
5'TGCCCTGAGGGCCTCTTCCAGCCTTCCTTC3' (SEQ ID NO: 5),
5'GGGTACATGGTGGTGGCGCCAGACAGCACNGTGTTGGC3' (SEQ ID NO: 6),
5'GCCAACACNGTGCTGTCTGGCGGCACCACCATGTACCC3' (SEQ ID NO: 7) and
5'TCGTACTCCTGCTTGCTGATCCACATCTG3' (SEQ ID NO: 8).
12. (canceled)
13. (currently amended) The method of claim 16, characterised in that the sample is taken from horse, goat, rabbit, dog, cat, chimpanzee, human ~~[[and/]]~~ or brown bear tissue.

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14 – 15. (canceled)

16. (currently amended) A method for genetic identification of biological species using a sample of biological material derived from a single species or from a heterogeneous mixture of species and/or subspecies, characterised in that it comprises:

(a) DNA extraction from the sample;

(b) amplification of ~~a one-or-more~~ region[[s]] of the DNA of the sample, said ~~one-or-more~~ region[[s]] ~~selected from the group consisting of a region~~ corresponding to the region between positions 1130 and 1473 of the human cytoplasmic beta-actin gene, ~~a region corresponding to the region between positions 1452 and 2063 of the human cytoplasmic beta-actin gene; a~~ region corresponding to the region between positions 2438 and 2680 of the human cytoplasmic beta-actin gene, and ~~a region corresponding to the region between positions 2642 and 2960 of the human cytoplasmic beta-actin gene,~~ said position numbers being relative to SEQ ID NO:9 ~~which comprises the full DNA sequence of the human locus HUMACCYBB Accession number M10277, version M10277.1, G1:177967, wherein (to be changed) primers hybridize to~~ conserved sequences between positions 1130 and 1473 of SEQ ID NO:9;

(c) analysis of the [[one or more]] amplified region[[s]] to determine the size in base-pairs and/or the precise DNA sequence thereof; and

(d) taxonomic identification of the biological species or subspecies from which the sample was derived by comparison of the size and/or DNA sequence ~~characteristics~~ of said [[one or more]] amplified region[[s]] with a database containing pre-established sizes and/or DNA sequences ~~characteristics~~ of the corresponding region[[s]] of the cytoplasmic beta-actin gene of a plurality of species and/or subspecies.

17. (currently amended) The method of claim 16, characterised in that in the amplification step gene segments of ~~evolutionarily evolutionary~~ divergent regions of the cytoplasmic beta-actin gene are amplified using DNA oligonucleotide primers corresponding to ranges of nucleotide positions in SEQ ID NO:9 having greater than 98% sequence identity among the species and sub-species present in the database having evolutionary DNA sequence conservation greater than 98% between species and subspecies.

18. (currently amended) The method of claim 16, characterised in that in the amplification step the segments to be amplified comprise the whole intronic DNA sequence and at least a portion of the flanking exonic sequences relative to SEQ ID NO:9, for each of the B, C, D and E introns as annotated in the GenBank Record of the human locus HUMACCYBB Accession number M10277, version M10277.1, G1:177967.

19. (currently amended) The method of claim 16, characterised in that in the amplification step primers are used ~~it uses a composition of universal primers~~ that hybridiz[[s]]e with one or more sequences within ~~regions of the cytoplasmic beta-actin gene selected from the group consisting of the regions~~ between positions 1130 ~~to 1191~~ and ~~1453 to 1473~~ of the cytoplasmic beta-actin gene, ~~the region between positions 1452 and 2063 of the cytoplasmic beta-actin gene, the region between positions 2438 and 2680 of the cytoplasmic beta-actin gene, and the region between positions 2642 and 2960 of the cytoplasmic beta-actin gene, said position numbers being relative to SEQ ID NO:9 which comprises the full DNA sequence of the human locus HUMACCYBB Accession number M10277, version M10277.1, G1:177967.~~

The following is a statement of the examiner's reasons for allowance. The prior art does

not teach or disclose the claimed method. As previously discussed, du Breuil et al. ("Quantitation of beta-actin-specific mRNA transcripts using xeno-competitive PCR," *Genome Res* 3:57-59, 1993) disclose a method of identifying one or more biological species, including human (*Homo sapiens*), by extracting RNA from animal samples, making DNA from the RNA, extracting the DNA (cDNA) and performing PCR. The PCR primers used are those that bind to the most conserved regions in human and rat beta-actin, such as regions in exon 3. The amplified DNA segments are compared in size to standard fragments on a gel (2% agarose gel), and the resulting sequences are compared to each other and to the known DNA sequences for each species tested. See pp. 57 and 58, left col. The divergent regions in the beta-actin gene are amplified (see Fig. 1).

du Breuil et al. do not disclose comparing the amplified DNA fragments to the sequences of the same regions of species included in a computer database. But, databases of gene sequence information were conventional at the time of the invention, as well as performing sequence comparisons to identify commonalities and differences among a set of related sequences. Nevertheless, du Breuil et al. do not disclose or suggest amplifying a DNA segment in the region of nucleotide positions 1130 – 1473 of SEQ ID NO:9, a region of the human beta-actin gene that includes the B intron.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Mon.-Wed. 8:30-6:00, Fri. 8:30-2:00, Thurs. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Examiner, Art Unit 1652
rk/2009-09-23

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656